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PATENT

Attorney Docket No.:

6056-279 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Patent application of

Clara Fronticelli

Serial No.:

09/787,216

Group Art Unit:

1653

Filed:

July 13, 2001

Examiner:

Karen C. Carlson

For:

POLYMERIC HEMOGLOBIN MUTANTS

Confirmation No.: 7591

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Non-Fee Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

This is in response to the office action mailed October 6, 2003. The action alleges that claims 1-24 are pending. Restriction has been required as between Group 1, claims 1-4 and 10-24, drawn to a human β -globin having substitution of Cys residues, and Group 2,

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.Oppox 1450, Alexandria, VA 22313-1450.

BY Marrin K. Smot

DATE:

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claims 5-9, drawn to nucleic acid encoding human β-globin gene having substitution of Cys residues.

Claims 11 and 12 were cancelled by a Preliminary Amendment filed March 14, 2001. Thus, for purposes of this response, applicant will treat Group 1 as containing claims 1-4, 10 and 13-24.

Applicant provisionally elects the claims of Group 1, claims 1-4, 10 and 13-24. The election is made with traverse.

Examiner alleges that the inventions of Groups 1 and 2 do not relate to a single inventive concept under PCT Rule 13.1, because under Rule 13.2, they lack the same or corresponding special technical feature. It is alleged that the claim groups lack the same or corresponding special technical feature because claim 1 is not novel. Examiner alleges that Karavitis *et al.* and Fronticelli *et al.* deprive claim 1 of novelty.

Claim 1 does not lack novelty over Karavitis *et al.* or Fronticelli *et al.* Claim 1 is directed to a human β-globin mutant polypeptide which comprises three mutations:

- 1) substitution or deletion of Cys at position 93;
- 2) substitution or deletion of Cys at position 112; and
- 3) substitution of a Cys for a non-Cys amino acid at one other position in the polypeptide.

Fronticelli et al. discloses four different β-globin polypeptides:

- (i) wild type;
- (ii) βC93A, wherein Cys at position 93 is substituted with Ala;
- (iii) βC112G, wherein Cys at position 1112 is substituted with Gly; and

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(iv) β C93A+ β C112G, a polypeptide containing both mutations of (ii) and (iii).

The Karavitis et al. abstract discloses the same (iii) and (iv) mutants.

The mutants of the references lack the additional Cys for a non-Cys amino acid substitution required by claim 1. Thus, claim 1 does not lack novelty over Karavitis *et al.* or Fronticelli *et al.* Reconsideration and withdrawal of the restriction requirement is earnestly solicited.

Respectfully submitted,

CLARA FRONTICELLI

DANIEL A. MONACO

Reg. No. 30,480

DRINKER, BIDDLE & REATH, LLP.

One Logan Square

18th and Cherry Streets

Philadelphia, PA 19103-6996

(215) 988-3312

(215) 988-2757 – fax

Attorney for the Applicant